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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,647	11/18/2004	Toshiaki Susuki	3883.021	5129

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EXAMINER	
ZEMAN, MARY K	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,647	SUSUKI ET AL.	
	Examiner	Art Unit	
	Mary K. Zeman	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *29 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-28* is/are pending in the application.

4a) Of the above claim(s) *28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-27* is/are rejected.

7)☒ Claim(s) *16-28* is/are objected to.

8)☒ Claim(s) *16-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/30/06 & 3/21/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 21-27 been renumbered 22-28. Two claims labeled 21 were submitted.Applicant's election with traverse of claims 16-27 in the reply filed on 8/29/07 is acknowledged. The traversal is on the ground(s) that claim 28 depends from claim 16 and should be rejoined. This is not found persuasive because the method of claim 16 does not require the program of claim 28, and the program of claim 28 cannot perform all the steps required by the methods. The computer program cannot perform the wet steps encompassed in the claims.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The IDS statements filed 3/21/05 and 10/30/06 have been entered and considered. Foreign language documents have been considered to the extent possible without a translation.

Drawings

The drawings of record are suitable to the examiner.

Specification

The preliminary amendment to the specification has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1—27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The steps of claim 16 fail to meet the goal of the preamble. At no point in the method steps of claim 16 are the specified target SNP domains linked to a disease susceptibility or drug responsiveness. None of the steps set forth how to identify populations or portions of genome which might be useful in identifying disease susceptibility target domains, nor do they set forth how to link any information generated with any type of known disease susceptibility. Similarly, the claims do not set forth where to look for domains which may be informative for drug responsiveness, or how to link any generated information to such a description. The steps of the method fail to set forth actually processes by which the goals are to be obtained. On what is a domain defined? The claim does not specify a genome or genomic information. How is the first continuous domain identified? What parameters, elements, or identifying characteristics are used in the definition of the domain? If the scanning domain is set before the "first step", then

the "setting a scanning domain" should be listed first. The steps actually performed in the "second step" and third step are entirely unclear.

Further, the metes and bounds of "disease susceptibility" and "drug responsiveness" are unclear. How is a SNP determined to be "related" to susceptibility? Which diseases? What constitutes a drug response, or a change in responsiveness? The specification fails to set forth clear definitions of what is intended to be encompassed by these terms.

The term "gradually narrowing down" in claim 16 is a relative term which renders the claim indefinite. The term "gradually narrowing down" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. If this step is intended to read on iterating a step over time, wherein each iteration results in a smaller localized domain, the claim limitation should be re-worded Similarly "narrowed down localized domain" is indefinite, as it is entirely unclear what it is, or how to obtain it.

The added limitation of claim 17 to the second step of claim 16 does not make sense. "wherein said second step comprises a step of setting a marker SNP for specifying said target SNP" is not clear. Where is it set? What is a marker? How does it aid in "narrowing down" said scanning domain?

In claim 18 the use of statistical analysis without specifying how the analysis is to be used, specifically, is unclear. How are these very generic types of genetic analysis intended to be used in specifying SNP that are related to disease or drug responsiveness? How is the generation of haplotypes used to "set said marker"?

In claim 19, the terms "genome domain", "clearly known" and "chromosomes whose functions can be predicted" are each indefinite. The metes and bounds of "genome domain" are unclear. A "domain" is not a standard subset for a genome. The "functions that are "clearly known" are not defined, nor is it clear what functions must be known to be included. Chromosomes do not have a function that can be predicted, but genes and open reading frames in the genomic sequences of a chromosome may have a published predicted function. However, any other prediction of function or predictions that "can" or "may" happen are not defined. How are they to be predicted?

Further in claim 19, how is the group for SNP selected for typing, and what samples are actually typed? No precious claims or steps obtain samples of actual DNA for use in a wet process. "using a wet process" is not descriptive of the SNP typing methods to be employed in the step.

Further in claim 19, probabilities are not "found" they are calculated. the term "significant deviation" is a relative term, and is not necessarily limited to the well known and understood scientific term of statistical significance. Claim 19 still fails to link any of the determined SNP information with disease susceptibility or drug responsiveness.

The limitations of claim 20 are entirely confusing. "wherein said third step comprises a seventh step.... in said fourth step... then repeating said fifth step" makes no sense at all. The Eighth and ninth steps in this claim are similarly unclear. It appears the numbering system of steps in all pending claims needs to be reworked such that further limitations to each step from claim 16 can be clearly and unambiguously understood. The phrase "the specified ration of the number of SNP's…" lacks antecedent basis in claim 19. The term " the deviated peak" lacks

antecedent basis in any previous claim. Claim 20 fails to link any SNP information to any disease susceptibility or drug responsiveness.

In claim 21, the further limitations to the "ninth" step are unclear, in that "all DNA samples lacks antecedent basis.

Claims 22 and 23 are each unclear and appear to be duplicative. Claim 24 contains parenthetical expressions which render the claim unclear. It is unclear whether the information included in the parentheses is intended to be step or limitation of the claim. As set forth above, probabilities are not "found" they are calculated and compared.

It is unclear how the limitations of claim 25 and 26 which set forth a "number of said SNP' are intended to limit the method of claim 16. is 10 or 3-5 supposed to be the end of the method? Or the number used in the first step? The limitation of claim 27 is grammatically incorrect as "moving" and "analyses" are in differing tenses. Further, the nature of the analysis is unclear.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-27 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to methods of "specifying" SNP information that may be related to disease susceptibility or drug responsiveness. The claims do not recite statutory methods under 35 USC 101. The recited claims do not set forth any transformation of matter, nor do they provide a concrete, tangible and useful result. The result of claim 16 is a "target SNP" which is merely a piece of sequence information/data which differs in a single

aspect from an unspecified reference. The SNP data is not linked to any particular disease susceptibility or drug response. The SNP information is not tangible or output to any user. The SNP data requires further interpretation or manipulation to be used or understood. The method does not produce a concrete result, as there is no assurance that any SNP will be found to be linked in any particular domain to the desired trait..

For claims including such excluded subject matter to be eligible, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomenon. Diehr, 450 U.S. at 187, 209 USPQ at 8 ("application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."); Benson, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it "has no substantial practical application").

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways:

1) The claimed invention "transforms" an article or physical object to a different state or thing.

2) The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation "is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application." AT&T, 172 F.3d at 1358-59, 50 USPQ2d at 1452... In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that the final result achieved by the claimed invention is "useful, tangible and concrete." (1) "USEFUL RESULT" For an invention to be "useful" it must satisfy the utility requirement of section 101. The USPTO's official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial and (iii) credible. MPEP § 2107 and Fisher, 421 F.3d at ___, 76 USPQ2d at 1230 (citing the Utility Guidelines with approval for interpretation of "specific" and "substantial"). (2) "TANGIBLE RESULT" The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. Benson, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had "no

substantial practical application."). "[A]n application of a law of nature or mathematical formula to a ... process may well be deserving of patent protection." Diehr, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); see also Corning, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . ."). In other words, the opposite meaning of "tangible" is "abstract." (3) "CONCRETE RESULT" Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. In re Swartz, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is "irreproducible" claim should be rejected under section 101). The opposite of "concrete" is unrepeatable or unpredictable.

See also: 1300 OG 142, 11/22/2005.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. The effective filing date for this application is 1/15/2003.

Claims 16-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Margus.

In view of the documented indefiniteness of the claims, the following rejections are applied.

Margus et al. (US 6,955,883 having priority to 3/26/02) discloses life science business models which obtain genomic information from a variety of populations and individuals, define domains or stretches of DNA which may contain SNP's of interest, identify SNP's within the domains, and specify targets. The targets may be associated with drug responsiveness or disease susceptibility. Wet steps of SNP typing may be performed, and statistical analyses of the significance of the findings can be performed. As such, Margus anticipates the methods of the claims.

Claims 16-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramnarayan et al..

Ramnarayan et al. (US 2003/0158672 having priority to 11/10/2000) discloses methods of using SNP information to generate 3 D models of drug targets. These methods obtain genomic information for genes or proteins which are targets of a defined drug from a variety of populations and individuals, define domains or stretches of DNA within those sequences which may contain SNP's of interest, identify SNP's within the domains, and specify targets. The targets may be associated with drug responsiveness. Wet steps of SNP typing may be performed, and statistical analyses of the significance of the findings can be performed. As such, Ramnarayan anticipates the methods of the claims.

Claims 16-27 are rejected under 35 U.S.C. 102(a) as being anticipated by Xu (GLAXO WO 2002/20835).

Xu et al. (WO 2002/20835, published 3/14/02: PTO-1449) discloses methods of associating phenotypes with haplotypes. These methods obtain genomic information from a variety of populations and individuals, define domains or stretches of DNA which may contain SNP's of interest, identify SNP's within the domains, and specify targets. The targets may be associated with phenotypes such as drug responsiveness or disease susceptibility. Wet steps of SNP typing may be performed, and statistical analyses of the significance of the findings can be performed. As such, Xu anticipates the methods of the claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Inoue. I. **SNP database** and establishment of personalized medicine. Nippon yakurigaku zasshi. Folia pharmacologica Japonica, (2002 Nov) Vol. 120, No. 1, pp. 41P-42P. with English Language Abstract only.

Smith et al. American journal of human genetics, (2004 May) Vol. 74, No. 5, pp. 1001-13. Electronic Publication: 2004-04-14.

Hua et al. The pharmacogenomics journal, (2005) Vol. 5, No. 3, pp. 183-92.

US 2003/0190652 De La Vega et al..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjie Moran can be reached on (571) 272 0720. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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/Mary K Zeman/

Primary Examiner, Art Unit 1631